PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

27 22

In re application of

Docket No: Q94121

Masao SUDOH, et al.

Appln. No.: 10/574,477

Group Art Unit: 1621

Confirmation No.: 2361

Examiner: Sadhakar KATAKAM

Filed: January 9, 2007

For:

DRUG CONTAINING (2R)-2-PROPYLOCTANOIC ACID AS THE ACTIVE

INGREDIENT

REQUEST FOR REFUND

MAIL STOP 16

Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant received a Non-Final Office Action from the United States Patent and Trademark Office dated May 23, 2007, in which the Office Action Summary indicated that the period for reply was set for three (3) months. The Office Action Summary also indicated that claims 1-34 are pending in the application and claims 1-31, 33-34 are subject to restriction and/or election requirement. Applicant electronically filed a Response to Restriction and Election of Species Requirement in the USPTO on August 22, 2007 and was charged \$450.00 for a two-month Extension of Time. Applicant believes the charged is incorrect since the Office Action Summary indicated a three (3) month period to reply and the Response was timely filed.

Applicant hereby respectfully requests a refund in the amount of \$450.00. This refund is to be credited to Deposit Account No. 19-4880.

REQUEST FOR REFUND U.S. Appln. No.: 10/574,477

Attorney Docket No.: Q94121

A copy of the Deposit Account Monthly Statement showing the charge to our account, and a copy of Office Action dated May 23, 2007 are enclosed.

Respectfully submitted,

Jennifer M. Haye

Registration No. 40,641

SUGHRUE MION, PLLC Telephone: (202) 293-7060 Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

65565 CUSTOMER NUMBER

Date: February 21, 2008

	Application No.	Applicant(s)				
·	10/574,477	SUDOH ET AL.				
Office Action Summary	Examiner	Art Unit				
	Sudhakar Katakam	1621				
- The MAILING DATE of this communication appears on the cover sheet with the correspondence address - Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Fellure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three manifes after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	NTE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim iii apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	N. sely filed the mating date of this communication. D (35 U.S.C.§ 133).				
Status						
1) Responsive to communication(s) filed on 03 Ar	1) Responsive to communication(s) filed on <u>03 April 2006</u> .					
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3) Since this application is in condition for allower	•	•				
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Disposition of Claims						
4) Claim(s) 1-34 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration,						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s)is/are objected to.						
8) Claim(s) <u>1-31, 33-34</u> are subject to restriction a	ind/or election requirement.					
Application Papers						
9) The specification is objected to by the Examine	rt.					
10) The drawing(s) filed on is/are: a) acce	epted or b) objected to by the i	Examiner.				
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the correct						
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form P10-152.				
Priority under 35 U.S.C. § 119						
12)☐ Acknowledgment is made of a claim for foreign a)☐ All b)☐ Some * c)☐ None of:)-(d) or (f).				
1. Certified copies of the priority documents						
2. Certified copies of the priority documents						
 Copies of the certified copies of the prior application from the International Bureau 		au in this National Stage				
* See the attached detailed Office action for a list		ed.				
See the Attached detailed Office delication of the	er mie adianida adpiad nas i adams	 -				
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Attachment(s) 1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summery	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Di	ate				
.3)	5) Notice of Informal F 6) Other:	амн стритации				



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/574,477	01/09/2007	Masao Sudoh	Q94121 ,	2361
23373 SÜGHRUE MI	7590 05/23/2007		EXAM	INER
	lvania avenue, n.W.		KATAKAM,	SUDHAKAR
SUITE 800 WASHINGTO	N DC 20037	DOCKETED	ART UNIT	PAPER NUMBER
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•		MAY 2 4 2007		
		٠.	MAIL DATE	DELIVERY MODE
			05/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

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St. Louis, MO 63197-9000

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CHARGES/ CREDITS FEE DATE POSTED CONTROL DESCRIPTION BALANCE DOCKET NO. (Serial, Patent, TM, Order) NO. MO. DAY YR. 40.00 173975.48 8021 Q103532 11817567 4 07 1011 300.00 173675.48 11848639 Q101179 4 07 111 9 173175.48 500.00 1111 11848639 Q101179 4 07 112 9 172975.48 200.00 1311 Q101179 11848639 9 4 07 113 300.00 172675.48 1011 Q103406 11848655 280 9 4 07 500.00 172175.48 Q103406 1111 11848655 4 107 281 9 171975.48 Q103406 1311 200.00 11848655 9 4 107 282 171935.48 40.00 Q101179 8021 11848639 302 9 4 07 171775.48 160.00 043507 - DJC 8021 6100312 9 4 107 653 171625.48 150.00 Q87643 1202 10533527 9 07 1 171505.48 120.00 Q83938 1251 10958340 9 819 07 171055.48 450.00 Q85455 1252 11013354 9 4 907 07 300.00 170755.48 1631 Q103484 11817592 9 4 07 913 1642 400.00 170355.48 0103484 11817592 9 914 4 07 200.00 170155.48 1633 Q103484 11817592 9 107 915 169855.48 300.00 0103683 1631 11817593 9 07 964 169455.48 400.00 0103683 1642 11817593 9 965 07 200.00 169255.48 0103683 1633 11817593 9 966 07 150.00 169105.48 0103683 1615 107 967 11817593 9 4 300.00 168805.48 1011 0103538 4 07 975 11848723 9 168305.48 500.00 1111 Q103538 976 11848723 4 9 07 168105.48 200.00 Q103538 1311 11848723 9 4 977 07 167105.48 1201 1000.00 11848723 0103538 4 978 9 07 120.00 166985.48 1251 Q59406 09648532 9 4 107 1039 166855.48 1618 130.00 0100222 9 4 07 11661136 -450.00 167305.48 257000 1252 11574477 9 4 07 167005.48 300.00 1011 0102069 11848748 9 4 07 1233 166505.48 500.00 1111 Q1020691 4 07 11848748 9 1234 166305.48 200.00 Q102069 1311 11848748 9 4 07 1235 164005.48 2300.00 Q102069 1202 ġ 11848748 4 07 1237 1252 450.00 163555+48 Q94121 10574477 9 4 07 8021 40.00 163515.48 Q103538 4 07 1378 11848723 9 40.00 8021 163475.48 Q102069 11848748 1440 9 4 07 163175.48 1631 300.00 Q103655 11817610 4 07 1502 9 162775.48 1642 400.00 Q103655 11817610 4 07 9 1503 1633 200.00 162575.48 11817610 Q103655 4 07 1504 TOTAL CREDITS CLOSING BALANCE TOTAL CHARGES OPENING BALANCE AN AMOUNT SUFFICIENT TO

MS020F (7/2007)

COVER ALL SERVICES REQUESTED MUST ALWAYS BE ON DEPOSIT

*** O.D. INDICATES OVERDRAWN

Application/Control Number: 10/574,477

Art Unit: 1621

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, 20-28, 33-34, drawn to a medicament comprising (2R)-2-propyloctanoic acid and a basic metal ion.

Group II, claim 18, drawn to a method of making a medicament comprising (2R)-2-propyloctanoic acid.

Group III, claim 19, drawn to a method of using a basic metal ion, which comprises (2R)-2-propyloctanoic acid.

Group IV, claim(s) 29-30, drawn to a container made of plastics, which is filled with (2R)-2-propyloctanoic acid, disodium hydrogen phosphate dodecahydrate and sodium hydroxide.

Group V, claim 31, drawn to a method of preventing and/or treating neurodegenerative diseases, nerve disorder or diseases in need of nerve regeneration, which comprise administering an effective amount of medicament comprising (2R)-2-propyloctanoic acid or a salt thereof and a basic metal ion.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is the "2-propyloctanic acid". This element is shown in the prior art (US 6,201,021) teaches the same ester system. Thus, there is no special technical feature connecting all the claims.

Page 3

Application/Control Number: 10/574,477

Art Unit: 1621

Because these inventions are independent or distinct for the reason given above and there would be a serious burden on the examiner if restriction were not required; because the inventions require a different field of search (see MPEP § 808.02) restriction for examination purposes as indicated is proper.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- A telephone call was not made because of the complex nature of claims.
- 4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Upon election of invention of groups I-V, applicant needs to elect a single disclosed species for examination purposes for either of the group elected. Claims will be examined to the extent they read on the elected species and closely related compounds. Applicant should identify all the claims that are readable on elected species.

Application/Control Number: 10/574,477

Art Unit: 1621

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

See claims and the examples disclosed in the specification.

Applicant must identify exact and full name of a species for the account of examination purpose and identify the claims readable upon.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- The following claims are generic:Claims 1-6 and 11-30 are generic.
- 7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature which is referred to Annex B of Appendix A1 of MPEP (Administrative

Application/Control Number: 10/574,477

Art Unit: 1621

Instructions under the PCT, "Unity of Invention"). Unity exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding claimed technical features. The express "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art ("Rule 13.2). The question of unity of invention has been reconsidered retroactively by the examiner in view of the search performed; a review of prior art (US 6,201,021) makes clear that the claimed "2-propyloctanic acid" is not novel over the prior art. Furthermore, these reference appear to demonstrate that the claimed "2-propyloctanic acid" analog does not define a contribution which each of the inventions, considered as a whole, makes over the prior art. Accordingly, the prior art of the record supports restriction of the claimed subject matter in to the groups as mentioned above.

- 8. A telephone call was not made because of the complex nature of claims.
- 9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

Art Unit: 1621

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richer can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SK

SANCEL BARTS
PRIMARY EXAMINER
GROUP 1200

Applicant(s)/Patent Under Reexamination Application/Control No. 10/574,477 SUDOH ET AL. Notice of References Cited Art Unit Examiner Page 1 of 1 Sudhakar Katakam 1621 U.S. PATENT DOCUMENTS Document Number Country Code-Number-Kind Code Date Classification Name MM-YYYY US-8,201,021 03-2001 514/558 Ohuchida et al. US-В US-C US-D US-Ε US-F US-G US-Н US-US-J USκ US-US-М FOREIGN PATENT DOCUMENTS Document Number Country Code-Number-Kind Code Dete MM-YYYY Country Name Classification O Р Q R S NON-PATENT DOCUMENTS Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) W

"A copy of this reference is not being furnished with this Office action, (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Tredemark Office PTO-892 (Rev. 01-2001)

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Notice of References Cited

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